TITLE 9. HEALTH SERVICES

CHAPTER 25. DEPARTMENT OF HEALTH SERVICES

EMERGENCY MEDICAL SERVICES

ARTICLE 13. TRAUMA CENTER DESIGNATION

<u>Section</u>	
R9-25-1301.	<u>Definitions</u>
R9-25-1302.	Eligibility for Designation
R9-25-1303.	Grace Period for Self-Designated Level I Trauma Facilities
R9-25-1304.	Initial Application and Designation Process
R9-25-1305.	Eligibility for Provisional Designation; Provisional Designation Process
R9-25-1306.	<u>Designation Renewal Process</u>
R9-25-1307.	Term of Designation
R9-25-1308.	Changes Affecting Designation Status
R9-25-1309.	Downgrading of Designation
R9-25-1310.	On-Site Survey for Designation as a Level IV Trauma Center Based on Compliance with
	the State Standards in Exhibit I
R9-25-1311.	<u>Inspections and Investigations</u>
R9-25-1312.	Denial or Revocation of Designation
R9-25-1313.	Trauma Center Responsibilities
R9-25-1314.	Confidentiality of Information
R9-25-1315.	Application Processing Time Periods
Table 1.	Application Processing Time Periods (in days)
Exhibit I.	Arizona Trauma Center Standards

ARTICLE 13. TRAUMA CENTER DESIGNATION

R9-25-1301. Definitions

The following definitions apply in this Article, unless otherwise specified:

- 1. "ACS" means the American College of Surgeons Committee on Trauma.
- 2. "ACS site visit" means an on-site inspection of a trauma facility conducted by ACS for purposes of determining compliance with ACS trauma facilities criteria, or ACS trauma facilities criteria and state standards, at the Level of designation sought.
- 3. "Administrative completeness time period" means the number of days from the Department's receipt of an application until the Department determines that the application contains all of the items of information required by rule to be submitted with an application.
- 4. "Applicant" means one of the following seeking initial or provisional designation, renewal of designation, extension of provisional designation, or downgrading of designation:
 - <u>a.</u> For a health care institution licensed under 9 A.A.C. 10, the licensee;
 - b. For a health care institution operated under federal or tribal laws, the administrative unit of the U.S. government or sovereign tribal nation operating the health care institution.
- 5. "ATLS" means the ACS Advanced Trauma Life Support Course.
- <u>6.</u> "Available" means accessible for use.
- 7. "Chief administrative officer" means an individual assigned to control and manage the day-to-day operations of a health care institution on behalf of the owner or the body designated by the owner to govern and manage the health care institution.
- 8. "CME" means continuing medical education courses for physicians.
- 9. "CT" means computed tomography.
- 10. "Current" means up-to-date and extending to the present time.
- 11. "CVP" means central venous pressure.
- 12. "Department" means the Arizona Department of Health Services.
- 13. "Designation" means a formal determination by the Department that a hospital or health care institution meets the standards to provide trauma services at a particular Level and is a trauma center.
- 14. "EMS" means emergency medical services.
- 15. "Health care institution" has the same meaning as in A.R.S. § 36-401.
- 16. "Hospital" has the same meaning as in A.A.C. R9-10-201.
- 17. "ICU" means intensive care unit.
- 18. "Immediately available" means that an individual is physically present in the stated location at the time of need by a trauma patient.

- 19. "In-house" means on the premises at the health care institution.
- 20. "ISS" means injury severity score, the sum of the squares of the abbreviated injury scale scores of the three most severely injured body regions.
- 21. "Licensee" means an owner approved by the Department, under 9 A.A.C. 10, to operate a health care institution.
- 22. "On-call" means assigned to respond and, if necessary, come to the health care institution when called by the health care institution.
- 23. "Owner" means one of the following:
 - <u>a.</u> For a health care institution licensed under 9 A.A.C. 10, the licensee;
 - b. For a health care institution operated under federal or tribal laws, the administrative unit of the U.S. government or sovereign tribal nation operating the health care institution.

24. "Person" means:

- <u>a.</u> <u>An individual;</u>
- <u>A business organization such as an association, cooperative, corporation, limited liability company, or partnership; or</u>
- <u>c.</u> <u>An administrative unit of the U.S. government, state government, or a political subdivision of the state.</u>
- 25. "Personnel" means an individual providing medical services, nursing services, or health-related services to a patient.
- 26. "PGY" means postgraduate year, a classification for residents in postgraduate training indicating the year that they are in during their post-medical-school residency program.
- 27. "Promptly available" means that an individual will be physically present in the stated location within a period of time that meets the needs of the patient.
- 28. "Self-designated Level I trauma facility" means a health care institution that as of July 1, 2004, met the definition of a Level I trauma center under A.A.C. R9-22-2101(F)(1).
- 29. "SICU" means surgical intensive care unit.
- 30. "Signature" means:
 - <u>a.</u> <u>A handwritten or stamped representation of an individual's name or a symbol intended to represent an individual's name, or</u>
 - b. An "electronic signature" as defined in A.R.S. § 44-7002.
- 31. "Substantial compliance" means that the nature or number of violations of the applicable standards for designation at a health care institution does not pose a direct risk to the life, health, or safety of trauma patients who require trauma services consistent with the Level of designation held or sought.

- 32. "Substantive review time period" means the number of days after completion of the administrative completeness time period during which the Department determines whether an application and applicant meet all substantive criteria required by rule for issuance of an approval.
- 33. "Trauma center" has the same meaning as in A.R.S. § 36-2225.
- 34. "Verification" means formal confirmation by ACS that a hospital or health care institution is providing trauma services and meets the ACS trauma facilities criteria for operation as a Level I, Level II, Level III, or Level IV trauma facility.
- 35. "Working day" means the period between 8:00 a.m. and 5:00 p.m. on a Monday, Tuesday, Wednesday, Thursday, or Friday that is not a state holiday.

R9-25-1302. Eligibility for Designation

- <u>A.</u> To be eligible to obtain designation for a health care institution, an applicant shall:
 - 1. <u>If applying for designation as a Level I trauma center:</u>
 - <u>a.</u> <u>Satisfy one of the following:</u>
 - i. Hold a current and valid regular license for the health care institution to operate as a hospital, issued by the Department under 9 A.A.C. 10, Article 2; or
 - ii. Be an administrative unit of the U.S. government or a sovereign tribal nation operating the health care institution as a hospital under federal or tribal law; and
 - b. Satisfy one of the following:
 - i. Hold current ACS verification for the health care institution as a Level I trauma facility; or
 - ii. Have current documentation issued by ACS stating that the health care institution meets the state standards for a Level I trauma center listed in Exhibit I;
 - <u>2.</u> <u>If applying for designation as a Level II trauma center:</u>
 - <u>a.</u> <u>Satisfy one of the following:</u>
 - i. Hold a current and valid regular license for the health care institution to operate as a hospital, issued by the Department under 9 A.A.C. 10,
 Article 2; or
 - ii. Be an administrative unit of the U.S. government or a sovereign tribal nation operating the health care institution as a hospital under federal or tribal law; and

- b. Satisfy one of the following:
 - i. Hold current ACS verification for the health care institution as a Level II trauma facility; or
 - ii. Have current documentation issued by ACS stating that the health care institution meets the state standards for a Level II trauma center listed in Exhibit I;
- <u>3.</u> <u>If applying for designation as a Level III trauma center:</u>
 - <u>a.</u> <u>Satisfy one of the following:</u>
 - i. Hold a current and valid regular license for the health care institution to operate as a hospital, issued by the Department under 9 A.A.C. 10,
 Article 2; or
 - ii. Be an administrative unit of the U.S. government or a sovereign tribal
 nation operating the health care institution as a hospital under federal or
 tribal law; and
 - b. Satisfy one of the following:
 - i. Hold current ACS verification for the health care institution as a Level
 III trauma facility; or
 - ii. Have current documentation issued by ACS stating that the health care institution meets the state standards for a Level III trauma center listed in Exhibit I; and
- 4. If applying for designation as a Level IV trauma center:
 - a. Satisfy one of the following:
 - i. Hold a current and valid regular license for the health care institution to operate, issued by the Department under 9 A.A.C. 10; or
 - <u>ii.</u> Be an administrative unit of the U.S. government or a sovereign tribal nation operating the health care institution under federal or tribal law;
 <u>and</u>
 - b. Satisfy one of the following:
 - i. Operate the health care institution in compliance with the state standards
 for designation as a Level IV trauma center listed in Exhibit I, as
 determined by the Department through an on-site survey conducted as
 described in R9-25-1310; or
 - ii. Hold current ACS verification for the health care institution as a Level

 IV trauma facility.

- **B.** To be eligible to retain designation for a health care institution, an owner shall:
 - 1. Maintain compliance with subsection (A), and
 - 2. Comply with the trauma center responsibilities in R9-25-1313.

R9-25-1303. Grace Period for Self-Designated Level I Trauma Facilities

- <u>A.</u> Within 90 days after the effective date of this Article, the owner of a self-designated Level I trauma facility who desires to obtain designation under this Article shall apply for initial designation as a Level I trauma center under R9-25-1304.
- <u>An owner who applies for designation based on eligibility under this Section shall identify in the application for initial designation which of the state standards listed in Exhibit I the owner agrees to comply with during the initial designation period:</u>
 - <u>1.</u> The state standards for a Level I trauma center, or
 - 2. The state standards for a Level II trauma center.
- <u>C.</u> For an application submitted by an owner described under subsection (A), the Department shall waive the eligibility requirement of R9-25-1302(A)(1)(b).
- <u>An owner described under subsection (A) who obtains initial designation as a Level I trauma</u>
 center and who desires to retain designation shall apply for renewal of designation under R9-25-1306.
- E. To obtain renewal of designation under R9-25-1306, an owner described under subsection (A) shall comply with R9-25-1302(A)(1)(b)(i) or (ii) and R9-25-1306.
- <u>F.</u> <u>During the term of an initial designation granted to an owner based on eligibility under this Section, the Department may:</u>
 - 1. <u>Inspect or investigate the owner's trauma center, as provided under R9-25-1311; and</u>
 - 2. Revoke the owner's designation, as provided under R9-25-1312.
- G. This Section expires on January 1, 2009.

R9-25-1304. Initial Application and Designation Process

- An applicant for initial designation shall submit to the Department an application including:
 - 1. An application form provided by the Department containing:
 - <u>a.</u> The name, address, and main telephone number of the health care institution for which the applicant seeks designation;
 - b. The applicant's name, address, and telephone number and, if available, fax number and e-mail address;
 - <u>c.</u> The name and telephone number and, if available, fax number and e-mail address
 of the chief administrative officer for the health care institution for which the
 applicant seeks designation;

- <u>d.</u> The designation Level for which the applicant is applying;
- e. If the applicant holds ACS verification for the health care institution for which designation is sought, the Level of ACS verification held and the effective and expiration dates of the ACS verification;
- f. Whether the applicant chooses to satisfy eligibility requirements based on:
 - <u>i.</u> ACS verification,
 - <u>ii.</u> Substantial compliance with the state standards in Exhibit I, or
 - <u>Eligibility for the grace period under R9-25-1303;</u>
- g. Unless the applicant is an administrative unit of the U.S. government or a sovereign tribal nation, the hospital or health care institution license number for the health care institution for which designation is sought;
- <u>h.</u> If applying for designation as a Level I, Level II, or Level III trauma center, the
 name and telephone number and, if available, fax number and e-mail address of
 the health care institution's trauma medical director;
- <u>i.</u> The name, title, address, and telephone number of the applicant's statutory agent
 or the individual designated by the applicant to accept service of process and
 subpoenas;
- <u>Attestation that the applicant knows all applicable requirements in A.R.S. Title</u>
 36, Chapter 21.1 and this Article;
- <u>Attestation that the information provided in the application, including the information in the documents attached to the application form, is accurate and complete; and
 </u>
- <u>1.</u> The dated signature of:
 - <u>i.</u> <u>If the applicant is an individual, the individual;</u>
 - <u>ii.</u> <u>If the applicant is a corporation, an officer of the corporation;</u>
 - iii. If the applicant is a partnership, one of the partners;
 - <u>iv.</u> If the applicant is a limited liability company, a manager or, if the limited liability company does not have a manager, a member of the limited liability company;
 - v. If the applicant is an association or cooperative, a member of the governing board of the association or cooperative;
 - vi. If the applicant is a joint venture, one of the individuals signing the joint venture agreement;

- <u>vii.</u> If the applicant is a governmental agency, the individual in the senior
 <u>leadership position with the agency or an individual designated in writing</u>
 by that individual; and
- viii. If the applicant is a business organization type other than those described in subsections (A)(1)(l)(ii) through (vi), an individual who is a member of the business organization;
- Unless the applicant is an administrative unit of the U.S. government or a sovereign tribal nation, a copy of the current regular hospital or health care institution license issued by the Department for the health care institution for which designation is sought;
- 3. If applying for designation based on ACS verification, documentation issued by ACS establishing that the applicant holds current ACS verification for the health care institution at the Level of designation sought and showing the effective and expiration dates of the ACS verification; and
- 4. If applying for designation as a Level I, Level II, or Level III trauma center based on compliance with the state standards in Exhibit I, current documentation issued by ACS establishing that the applicant's health care institution meets the state standards listed in Exhibit I for the Level of designation sought.
- **B.** The Department shall process an application as provided in R9-25-1315.
- C. The Department shall approve designation if the Department determines that an applicant is eligible for designation as described in R9-25-1302 and, if the applicant is applying for designation as a Level IV trauma center based on compliance with the state standards in Exhibit I, has corrected any deficiencies identified during an on-site survey of the health care institution.

R9-25-1305. Eligibility for Provisional Designation; Provisional Designation Process

- A. The owner of a health care institution may apply for one 18-month provisional designation if:
 - 1. The owner's health care institution has been providing services as a trauma facility for less than 12 consecutive months when the owner applies for designation; and
 - 2. The owner does not meet the requirements in R9-25-1302(A)(1)(b), (A)(2)(b), or (A)(3)(b).
- **B.** To be eligible to obtain provisional designation for a health care institution, an applicant shall:
 - 1. Satisfy one of the following:
 - a. Hold a current and valid regular license for the health care institution to operate as a hospital, issued by the Department under 9 A.A.C. 10, Article 2; or

- <u>b.</u> <u>Be an administrative unit of the U.S. government or a sovereign tribal nation</u> operating the health care institution as a hospital under federal or tribal law; and
- Operate the trauma facility in substantial compliance with the state standards listed in Exhibit I for the Level of designation sought.
- C. An applicant for provisional designation shall submit to the Department an application including:
 - 1. An application form that contains the information and items listed in R9-25-1304(A)(1)(a) through (A)(1)(d), (A)(1)(g) through (A)(1)(l), and (A)(2); and
 - 2. Attestation that during the term of the provisional designation, the applicant shall:
 - a. Apply for ACS verification for the trauma center; and
 - <u>b.</u> Provide to the Department, within 30 days after applying for ACS verification,
 <u>documentation issued by ACS establishing that the applicant has applied for ACS</u> verification.
- <u>D.</u> The Department shall process an application submitted under this Section as provided in R9-25-1315.
- E. The Department shall approve provisional designation if the Department determines that an applicant is eligible for provisional designation as described in subsection (B).
- <u>F.</u> To be eligible to retain provisional designation for a health care institution, an owner shall:
 - 1. Maintain compliance with subsection (B);
 - 2. Comply with the trauma center responsibilities in R9-25-1313;
 - 3. Apply for ACS verification for the trauma center; and
 - 4. Provide to the Department, within 30 days after applying for ACS verification, documentation issued by ACS establishing that the owner has applied for ACS verification.
- <u>G.</u> An owner who holds provisional designation and who desires to retain designation shall, before the expiration date of the provisional designation:
 - 1. If the owner is eligible for designation under R9-25-1302(A)(1)(b), (A)(2)(b), or (A)(3)(b), apply for initial designation under R9-25-1304; or
 - 2. If the owner is not yet eligible for designation under R9-25-1302(A)(1)(b), (A)(2)(b), or (A)(3)(b), apply for an extension of the provisional designation under subsection (H).
- An owner who holds provisional designation and who will not be eligible for designation under R9-25-1302(A)(1)(b), (A)(2)(b), or (A)(3)(b) on the expiration date of the provisional designation may apply to the Department, on a form provided by the Department, for one 180-day extension of the provisional designation and shall include with the application documentation issued by ACS showing the owner's progress in obtaining an ACS site visit.

- <u>I.</u> The Department shall grant an extension if an owner has provided documentation issued by ACS:
 - 1. Establishing that the owner has applied for ACS verification; and
 - 2. Showing the owner's progress in obtaining an ACS site visit.
- <u>J.</u> The Department may:
 - 1. <u>Inspect or investigate, under R9-25-1311, a trauma center that is the subject of a provisional designation; and</u>
 - 2. Revoke, as provided under R9-25-1312, a provisional designation.

R9-25-1306. Designation Renewal Process

- At least 60 and no more than 90 days before the expiration date of a current designation, an applicant for designation renewal shall submit to the Department an application including:
 - 1. An application form that contains the information listed in R9-25-1304(A)(1);
 - 2. <u>If applying for renewal of designation as a Level II, Level II, or Level III trauma center</u> based on compliance with the state standards in Exhibit I, one of the following:
 - a. Documentation issued by ACS no more than 60 days before the date of application establishing that the applicant's trauma center meets the state standards listed in Exhibit I for the Level of designation sought; or
 - <u>b.</u> Documentation issued by ACS establishing that the applicant has applied for
 ACS verification for the trauma center, at the Level corresponding to the Level of
 designation sought, for the three-year period directly following the expiration of
 the applicant's current state designation; and
 - 3. <u>If applying for renewal of designation based on ACS verification, documentation issued</u> by ACS establishing that the applicant:
 - a. Holds ACS verification for the trauma center, at the Level corresponding to the
 Level of designation sought, for the three-year period directly following the
 expiration of the applicant's current ACS verification and state designation; or
 - <u>b.</u> Has applied for ACS verification for the trauma center, at the Level
 corresponding to the Level of designation sought, for the three-year period
 directly following the expiration of the applicant's current ACS verification and
 state designation.
- **B.** The Department shall process an application as provided in R9-25-1315.
- <u>C.</u> The Department shall renew designation if the Department determines that:
 - 1. The applicant is eligible to retain designation as described in R9-25-1302(B); and
 - 2. If the applicant is applying for renewal of designation as a Level IV trauma center based on compliance with the state standards in Exhibit I, the applicant has:

- a. Operated the trauma center in substantial compliance with the state standards in
 Exhibit I during the most recent designation period; and
- <u>b.</u> <u>Corrected any deficiencies identified during an on-site survey of the trauma</u> center.
- <u>D.</u> The Department shall not renew designation based on ACS verification or ACS's determination of compliance with the state standards in Exhibit I until the Department receives documentation that complies with subsection (A)(2)(a) or (A)(3)(a).

R9-25-1307. Term of Designation

- <u>A.</u> The Department shall issue initial designation or renewal of designation:
 - When based on ACS verification, with a term beginning on the date of issuance and ending on the expiration date of the ACS verification upon which designation is based; and
 - When based on compliance with the state standards in Exhibit I or eligibility under R9 25-1303, with a term beginning on the date of issuance and ending three years later.
- <u>B.</u> The Department shall issue a provisional designation with a term beginning on the date of issuance and ending 18 months later.
- C. The Department shall issue a downgraded designation with a term beginning on the date of issuance and ending on the expiration date of the designation issued before the application for downgrading of designation under R9-25-1309.
- <u>D.</u> <u>If an applicant submits an application for renewal of designation as described in R9-25-1306 at least 60 and no more than 90 days before the expiration date of the current designation, or submits an application for extension of provisional designation as described in R9-25-1305 before the expiration date of the provisional designation, the current designation does not expire until the Department has made a final determination on the application for renewal of designation or extension of provisional designation.</u>

R9-25-1308. Changes Affecting Designation Status

- At least 30 days before the date of a change in a trauma center's name, the owner of the trauma center shall send the Department written notice of the name change.
- **B.** At least 90 days before a trauma center ceases to offer trauma services, the owner of the trauma center shall send the Department written notice of the intention to cease offering trauma services and the desire to relinquish designation.
- <u>Within 30 days after the date of receipt of a notice described in subsection (A) or (B), the Department shall:</u>

- 1. For a notice described in subsection (A), issue an amended designation that incorporates the name change but retains the expiration date of the current designation; or
- 2. For a notice described in subsection (B), send the owner written confirmation of the voluntary relinquishment of designation, with an effective date consistent with the written notice.
- <u>D.</u> The owner of a trauma center shall notify the Department in writing within three working days after:
 - 1. The trauma center's hospital or health care institution license expires or is suspended, revoked, or changed to a provisional license;
 - A change in the trauma center's ACS verification status, if designation is based on ACS verification; or
 - 3. A change in the ability to offer trauma services in substantial compliance with the applicable standards for designation.

R9-25-1309. Downgrading of Designation

- An owner of a Level I, Level II, or Level III trauma center who desires to offer trauma services at a Level of designation that requires fewer resources than the current Level of designation shall, at least 90 days before ceasing to provide trauma services consistent with the current Level of designation, send the Department an application for downgrading of the trauma center's Level of designation, including:
 - 1. The name, address, and main telephone number of the health care institution for which the applicant seeks downgrading of designation;
 - 2. The applicant's name, address, and telephone number and, if available, fax number and email address;
 - 3. A list of the ACS or state criteria, as applicable, for the current Level of designation with which the applicant no longer intends to comply;
 - 4. An explanation of the changes being made in the trauma center's resources or operations related to each criterion listed under subsection (A)(3);
 - <u>5.</u> The state Level of designation requested;
 - 6. Attestation that the applicant knows the state standards for the Level of designation requested and will ensure that the trauma center is operated in substantial compliance with those state standards if downgraded designation is issued;
 - 7. Attestation that the information provided in the application is accurate and complete; and
 - 8. The dated signature of the applicant, as prescribed in R9-25-1304(A)(1)(1).
- **B.** The Department shall process an application as provided in R9-25-1315.

- <u>C.</u> The Department shall issue a downgraded designation if the Department determines that, with the changes being made in the trauma center's resources and operations, the trauma center will be operated in substantial compliance with the state standards for the Level of designation requested.
- **D.** The Department may:
 - 1. <u>Inspect or investigate, under R9-25-1311, a trauma center that is the subject of a downgraded designation; and</u>
 - 2. Revoke, as provided under R9-25-1312, a downgraded designation.
- **E.** An owner who holds downgraded designation shall, before the expiration date of the downgraded designation:
 - 1. If the owner desires to retain designation at the Level of the downgraded designation, apply for renewal of designation under R9-25-1306; or
 - 2. If the owner desires to obtain designation at a Level other than the Level of the downgraded designation, apply for initial designation under R9-25-1304.

R9-25-1310. On-Site Survey for Designation as a Level IV Trauma Center Based on Compliance with the State Standards in Exhibit I

- A. Before issuing initial or renewal designation to an applicant applying for designation as a Level

 IV trauma center based on compliance with the state standards in Exhibit I, the Department shall complete an announced on-site survey of the applicant's health care institution that includes:
 - 1. Reviewing equipment and the physical plant;
 - <u>2.</u> <u>Interviewing personnel; and</u>
 - 3. Reviewing:
 - <u>a.</u> <u>Medical records;</u>
 - <u>b.</u> Patient discharge summaries;
 - <u>c.</u> <u>Patient care logs;</u>
 - <u>d.</u> Personnel rosters and schedules;
 - e. Performance-improvement-related documents other than peer review documents privileged under A.R.S. §§ 36-445.01 and 36-2403, including reports prepared by a hospital as required under R9-10-204(B)(2) and the supporting documentation for the reports; and
 - <u>f.</u> Other documents relevant to the provision of trauma services as a Level IV trauma center and that are not privileged under federal or state law.
- **B.** A Department surveyor shall make a verbal report of findings to an applicant upon completion of an on-site survey.

- <u>C.</u> Within 30 days after completing an on-site survey, the Department shall send to an applicant a written report of the Department's findings, including a list of any deficiencies identified during the on-site survey and, unless subsection (F) applies, a request for a written corrective action plan.
- <u>Mithin 10 days after receiving a request for a written corrective action plan, an applicant shall submit to the Department a written corrective action plan that includes for each identified deficiency:</u>
 - 1. A description of how the deficiency will be corrected, and
 - <u>A date of correction for the deficiency.</u>
- **E.** The Department shall accept a written corrective action plan if it:
 - 1. Describes how each identified deficiency will be corrected to bring the health care institution into compliance with the applicable standards for designation, and
 - 2. <u>Includes a date for correcting each deficiency as soon as practicable based upon the actions necessary to correct the deficiency.</u>
- <u>F.</u> The Department shall provide an applicant an opportunity to correct the deficiencies identified during an on-site survey unless the Department determines that the deficiencies are:
 - 1. Committed with knowledge that they are deficiencies;
 - 2. Evidence of a pattern of noncompliance with the applicable standards for designation; or
 - 3. A risk to any person; the public health, safety, or welfare; or the environment.

R9-25-1311. Inspections and Investigations

- A. If the Department determines based upon data collected by the Department or receives a complaint alleging that a trauma center is not being operated in compliance with the standards for designation, the Department shall conduct an investigation of the trauma center.
 - 1. The Department may conduct an unannounced on-site inspection as part of an investigation.
 - Within 30 days after completing an investigation, the Department shall send to the owner of the trauma center investigated a written report of the Department's findings, including a list of any deficiencies identified during the investigation and, unless subsection (D) applies, a request for a written corrective action plan.
- **B.** Within 10 days after receiving a request for a written corrective action plan, an owner shall submit to the Department a written corrective action plan that includes for each identified deficiency:
 - 1. A description of how the deficiency will be corrected, and
 - 2. A date of correction for the deficiency.
- <u>C.</u> The Department shall accept a written corrective action plan if it:

- 1. Describes how each identified deficiency will be corrected to bring the trauma center into compliance with the applicable standards for designation, and
- 2. Includes a date for correcting each deficiency as soon as practicable based upon the actions necessary to correct the deficiency.
- <u>D.</u> The Department shall provide the owner of a trauma center an opportunity to correct the deficiencies identified during an investigation unless the Department determines that the deficiencies are:
 - 1. Committed with knowledge that they are deficiencies;
 - 2. Evidence of a pattern of noncompliance with the applicable standards for designation; or
 - 3. A risk to any person; the public health, safety, or welfare; or the environment.

R9-25-1312. Denial or Revocation of Designation

- <u>A.</u> The Department may deny or revoke designation if an applicant or owner:
 - 1. Has provided false or misleading information to the Department;
 - 2. Does not meet the eligibility requirements of R9-25-1302(A) or (B);
 - 3. Fails to submit to the Department all of the information requested in a written request for additional information within the time prescribed in R9-25-1315 and Table 1;
 - 4. Fails to submit a written corrective action plan as requested and required under R9-25-1310 or R9-25-1311;
 - 5. Fails to comply with a written corrective action plan accepted by the Department under R9-25-1310 or R9-25-1311;
 - 6. Fails to allow the Department to enter the health care institution's premises, to interview personnel, or to review documents other than documents privileged under federal or state law; or
 - 7. Fails to comply with any provision in A.R.S. Title 36, Chapter 21.1 or this Article.
- **B.** If the Department denies or revokes designation, the Department shall send to the applicant or owner a written notice setting forth the information required under A.R.S. § 41-1092.03.
 - 1. An applicant or owner may file a written notice of appeal with the Department within 30 days after receiving a notice of denial or revocation, as provided in A.R.S. § 41-1092.03.
 - 2. An appeal shall be conducted according to A.R.S. Title 41, Chapter 6, Article 10.

R9-25-1313. Trauma Center Responsibilities

The owner of a trauma center shall ensure that:

1. The trauma center is operated in substantial compliance with the applicable standards for designation;

- <u>Data related to the trauma services provided at the trauma center are submitted to the Department's Trauma Registry as required by the Department;</u>
- 3. The owner and the trauma center staff comply with the provisions of A.R.S. Title 36, Chapter21.1 and this Article; and
- 4. The owner and the trauma center staff comply with all applicable federal and state laws relating to confidentiality of information.

R9-25-1314. Confidentiality of Information

The Department shall comply with all applicable federal and state laws relating to confidentiality of information.

R9-25-1315. Application Processing Time Periods

- A. The application processing time periods for each type of approval granted by the Department under this Article are listed in Table 1 and may be extended through a written agreement between an applicant and the Department.
- <u>B.</u> The Department shall, within the administrative completeness time period specified in Table 1, review each application submitted for administrative completeness.
 - If an application is incomplete, the Department shall send to the applicant a written notice
 listing each deficiency and the information or items needed to complete the application.
 - 2. If an applicant fails to submit to the Department all of the information or items listed in a notice of deficiencies within the time period specified in Table 1, the Department shall consider the application withdrawn.
- <u>C.</u> After determining that an application is administratively complete, the Department shall review the application for substantive compliance with the requirements for approval.
 - 1. The Department shall complete its substantive review of each application, and send an applicant written notice of approval or denial, within the substantive review time period specified in Table 1.
 - As part of the substantive review for an application for initial designation or renewal of designation as a Level IV trauma center based on compliance with the state standards in Exhibit I, the Department shall conduct an announced on-site survey of the health care institution or trauma center as described in R9-25-1310.
 - 3. An applicant for renewal of designation who submitted documentation of the applicant's having applied for ACS verification as permitted under R9-25-1306(A)(2)(b) or (A)(3)(b) shall submit to the Department during the substantive review time period documentation that complies with R9-25-1306(A)(2)(a) or (A)(3)(a).

- 4. During the substantive review time period, the Department may make one written request for additional information, listing the information or items needed to determine compliance with the requirements for approval.
- 5. For an application for initial designation or renewal of designation as a Level IV trauma center based on compliance with the state standards in Exhibit I, a written request for additional information may include a request for a corrective action plan to correct any deficiencies identified during an on-site survey of the health care institution or trauma center.
- 6. If an applicant fails to submit to the Department all of the information or items listed in a written request for additional information, including, if applicable, a corrective action plan, within the time period specified in Table 1, the Department shall deny the application.

D. In applying this Section, the Department shall:

- In calculating an applicant's time to respond, begin on the postmark date of a notice of deficiencies or written request for additional information and end on the date that the Department receives all of the information or documents requested in the notice of deficiencies or written request for additional information; and
- 2. In calculating the Department's time periods, not include any time during which the Department is waiting for an applicant to submit information or documents to the Department as requested by the Department in a notice of deficiencies or written request for additional information.
- **E.** If the Department denies an application, the Department shall send to the applicant a written notice of denial setting forth the information required under A.R.S. § 41-1092.03.
 - 1. An applicant may file a written notice of appeal with the Department within 30 days after receiving the notice of denial, as provided in A.R.S. § 41-1092.03.
 - 2. An appeal shall be conducted according to A.R.S. Title 41, Chapter 6, Article 10.

Table 1. Application Processing Time Periods (in days)

Type of Approval	Department's	Applicant's Time to	Department's	Applicant's Time to
	Administrative	Respond to Notice	Substantive Review	Respond to Written
	Completeness Time	of Deficiencies	Time Period	Request for
	<u>Period</u>			<u>Information</u>
Initial Designation	<u>30</u>	<u>30</u>	<u>90</u>	<u>60</u>
(R9-25-1304)				
Provisional	<u>30</u>	<u>30</u>	<u>90</u>	<u>60</u>

Draft, 11/16/04

Designation				
(R9-25-1305)				
Extension of	<u>15</u>	<u>30</u>	<u>15</u>	<u>30</u>
<u>Provisional</u>				
<u>Designation</u>				
(R9-25-1305)				
Renewal of	<u>30</u>	<u>30</u>	<u>90</u>	<u>120</u>
<u>Designation</u>				
(R9-25-1306)				
Downgrading of	<u>30</u>	<u>30</u>	<u>90</u>	<u>60</u>
<u>Designation</u>				
(R9-25-1309)				

EXHIBIT I. ARIZONA TRAUMA CENTER STANDARDS

E = Essential and required

	Torres Facilità e Caldania		<u>Levels</u>			
	<u>Trauma Facilities Criteria</u>	Ī	II	III	IV	
<u>A.</u>	Institutional Organization					
	1. Trauma program	<u>E</u>	<u>E</u>	<u>E</u>	=	
	2. Trauma service	<u>E</u>	<u>E</u>	<u>E</u>	=	
	3. Trauma team	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>	
	4. Trauma program medical director	<u>E</u>	<u>E</u>	E	=	
	5. Trauma multidisciplinary committee	<u>E</u>	<u>E</u>	E	=	
	6. Trauma coordinator/trauma program manager	E	E	E	Ē	
В.	Hospital Departments/Divisions/Sections	-	,			
	1. Surgery	<u>E</u>	<u>E</u>	E	=	
_	2. Neurological surgery	<u>E</u>	<u>E</u>	<u> </u>	_	
	a. Neurosurgical trauma liaison	E	<u>E</u>	=	=	
-	3. Orthopaedic surgery	E	<u>E</u>	<u>E</u>	_	
-	a. Orthopaedic trauma liaison	<u>E</u>	<u>E</u>	<u>E</u>	=	
-	4. Emergency medicine	<u>E</u>	<u>E</u>	<u>E</u>		
_	5. Anesthesia	E	E	E	=	
C.	Clinical Capabilities			-		
<u>C.</u>	1. Published on-call schedule for each listed specialty in (C)(2) and (3)	E	E	<u>E</u>		
	2. Specialty immediately available 24 hours/day	브	브	브	=	
	a. General surgery	E	E	<u>E</u>		
		<u>E</u>	<u>E</u>		=	
-	•		<u>E</u>	=	=	
	<u> </u>	<u>E</u>	<u>E</u>	<u>-</u>	=	
-	b. Anesthesia	<u>E</u>	<u>E</u>	<u>E</u>	=	
-	c. Emergency medicine ¹	<u>E</u>	<u>E</u>	<u>E</u>	=	
	3. On-call and promptly available 24 hours/day					
-	a. Cardiac surgery	<u>E</u>	<u>-</u>	=	=	
	b. Hand surgery ²	<u>E</u>	<u>E</u>	=	=	
	c. Microvascular/replant surgery ²	<u>E</u>	<u>-</u>	=	=	
	d. Neurologic surgery	<u>E</u>	<u>E</u>	=	=	
	i. Dedicated to one hospital or back-up call	<u>E</u>	<u>E</u>	=	=	
	e. Obstetrics/gynecologic surgery	<u>E</u>	<u>E</u>	=	=	
	f. Ophthalmic surgery	<u>E</u>	<u>E</u>	=	=	
	g. Oral/maxillofacial surgery	<u>E</u>	<u>E</u>	=	=	
	h. Orthopaedic surgery	<u>E</u>	<u>E</u>	<u>E</u>	=	
	i. Dedicated to one hospital or back-up call	<u>E</u>	<u>E</u>	<u>=</u>	=	
	i. Plastic surgery	<u>E</u>	<u>E</u>	<u>=</u>	=	
	j. Critical care medicine	<u>E</u>	<u>E</u>	=	=	
	k. Radiology	<u>E</u>	<u>E</u>	<u>E</u>	=	
	1. Thoracic surgery	<u>E</u>	<u>E</u>	=	=	
<u>D.</u>	Clinical Qualifications					
	1. General/Trauma Surgeon					
	a. Current Board Certification ³	<u>E</u>	<u>E</u>	<u>E</u>	Ξ	
	b. 16 hours CME/year	<u>E</u>	<u>E</u>	=	<u> </u>	
	c. ATLS certification	<u>E</u>	<u>E</u>	Ē	E	
	d. Peer review committee attendance > 50%	E	<u>E</u>	<u>E</u>	=	
	e. Multidisciplinary committee attendance	E	E	E	=	
	2. Emergency Medicine					
	a. Board certification ³	<u>E</u>	<u>E</u>	_	=	

I T I I C I C I C I C I C I C I C I C I	г			
b. Trauma education – 16 hours CME/year	<u>E</u>	<u>E</u>	<u>-</u>	=
c. ATLS certification ⁴	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
d. Peer review committee attendance > 50%	<u>E</u>	<u>E</u>	<u>E</u>	=
e. Multidisciplinary committee attendance	<u>E</u>	<u>E</u>	<u>E</u>	=
3. Neurosurgery				
a. Current board certification	<u>E</u>	<u>E</u>	=	=
b. 16 hours CME/year	<u>E</u>	<u>E</u>	=	=
<u>c. Peer review committee attendance > 50%</u>	<u>E</u>	<u>E</u>	<u>E</u>	_
d. Multidisciplinary committee attendance	<u>E</u>	<u>E</u>	<u>E</u>	=
4. Orthopaedic Surgery				
a. Board certification	<u>E</u>	<u>E</u>	=	=
b. 16 hours CME in skeletal trauma	<u>E</u>	<u>E</u>	=	=
c. Peer review committee attendance > 50%	<u>E</u>	<u>E</u>	<u>E</u>	=
d. Multidisciplinary committee attendance	<u>E</u>	<u>E</u>	<u>E</u>	=
E. Facilities/Resources/Capabilities				
1. Volume Performance ⁵	<u>E</u>	Ξ	_	=
2. Presence of surgeon at resuscitation (immediately available) ⁶	<u>E</u>	Ē	=	=
3. Presence of surgeon at resuscitation (promptly available)	=	=	E	=
4. Presence of surgeon at operative procedures	Ē	Ē	E	Ē
5. Emergency Department			_	_
a. Personnel				
i. Designated physician director	E	E	<u>E</u>	
b. Resuscitation Equipment for Patients of All Ages	_	_	_	_
i. Airway control and ventilation equipment	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
ii. Pulse oximetry	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
iii. Suction devices	<u>E</u>	<u>E</u>	E	<u>E</u>
iv. Electrocardiograph-oscilloscope-defibrillator	<u>E</u>	<u>E</u>	E	E
v. Internal paddles	<u>E</u>	<u>E</u>	E	
vi. CVP monitoring equipment	<u>E</u>	<u>E</u>	<u>E</u>	=
vii. Standard intravenous fluids and administration sets	<u>E</u>	<u>E</u>	<u>E</u>	<u>-</u> <u>E</u>
viii. Large-bore intravenous catheters	<u>E</u>	<u>E</u>	E	E
	<u> 15</u>	<u> 1:</u>	<u> </u>	<u> L</u>
ix. Sterile Surgical Sets for (1) Airway control/cricothyrotomy	Е	E	<u>E</u>	<u>E</u>
	<u>E</u>	<u>E</u>	<u>E</u>	_
(2) Thoracostomy	<u>E</u>	<u>E</u>		<u>E</u>
(3) Venous cutdown	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
(4) Central line insertion	<u>E</u>	<u>E</u>	<u>E</u>	<u> </u>
(5) Thoracotomy	<u>E</u>	<u>E</u>	<u>E</u>	=
(6) Peritoneal lavage	<u>E</u>	<u>E</u>	<u>E</u>	=
x. Arterial catheters	<u>E</u>	<u>E</u>	<u>-</u>	<u>-</u>
xi. Drugs necessary for emergency care	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
xii. X-ray availability 24 hours/day	<u>E</u>	<u>E</u>	<u>E</u>	=
<u>xiii. Cervical traction devices</u>	<u>E</u>	<u>E</u>	<u>E</u>	<u>-</u>
xiv. Broselow tape	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
xv. Thermal Control Equipment				
(1) For patient	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
(2) For fluids and blood	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
xvi. Rapid infuser system	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
xvii. Qualitative end-tidal CO ₂ determination	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
c. Communication with EMS vehicles	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
d. Capability to resuscitate, stabilize, and transport pediatric patients ²	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
6. Operating Room				
a. Immediately available 24 hours/day ⁸	<u>E</u>	Ξ	=	<u> </u>
b. Personnel				

		1	T	T
i. In-house 24 hours/day	<u>E</u>	=	=	=
ii. Available 24 hours/day	=	<u>E</u>	<u>E</u>	=
c. Age-Specific Equipment				
i. Cardiopulmonary bypass	<u>E</u>	<u> </u>	<u> </u>	<u> =</u>
ii. Operating microscope	E	=	_	<u>=</u>
d. Thermal Control Equipment				
i. For patient	E	E	E	E
ii. For fluids and blood	E	E	E	E
e. X-ray capability including C-arm image intensifier	E	E	<u>E</u>	_=_
f. Endoscopes, bronchoscope	E	E	<u>E</u>	_
g. Craniotomy instruments	E	E	브	=
h. Equipment for long bone and pelvic fixation	E	<u>E</u>	<u> </u>	=
* * * * * * * * * * * * * * * * * * * *			<u>E</u>	<u>-</u>
i. Rapid infuser system	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
7. Postanesthetic Recovery Room (SICU is acceptable)				
a. Registered nurses available 24 hours/day	<u>E</u>	<u>E</u>	<u>E</u>	=
b. Equipment for monitoring and resuscitation	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
c. Intracranial pressure monitoring equipment	<u>E</u>	<u>E</u>	_	=
i. Pulse oximetry	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
ii. Thermal control	E	<u>E</u>	<u>E</u>	<u>E</u>
8. Intensive or Critical Care Unit for Injured Patients				
a. Registered nurses with trauma training	E	E	E	-
b. Designated surgical director or surgical co-director	E	E	E	
c. Surgical ICU service physician in-house 24 hours/day ⁹	E		<u> =</u>	
d. Surgically directed and staffed ICU service ²	E	 	=	=
e. Equipment for monitoring and resuscitation	E	<u>-</u> <u>E</u>	<u>E</u>	=
			<u>E</u>	=
f. Intracranial pressure monitoring equipment	<u>E</u>	<u>E</u>	<u>-</u>	=
g. Pulmonary artery monitoring equipment	<u>E</u>	<u>E</u>	<u>E</u>	=
9. Respiratory Therapy Services				
a. Available in-house 24 hours/day	<u>E</u>	<u>E</u>	=	=
b. On-call 24 hours/day	=	=	<u>E</u>	=
10. Radiological Services (Available 24 hours/day)				
a. In-house radiology technologist	<u>E</u>	<u>E</u>	<u>=</u>	<u>=</u>
b. Angiography	E	E	=	=
c. Sonography	E	E	Ē	_
d. Computed tomography	E	E	E	-
i. In-house CT technician	E	-	-	_
e. Magnetic resonance imaging	E	-		
11. Clinical Laboratory Service (Available 24 hours/day)	브	-		<u> </u>
a. Standard analyses of blood, urine, and other body fluids, including	<u>E</u>	<u>E</u>	<u>E</u>	E
microsampling when appropriate				
b. Blood typing and cross-matching	<u>E</u>	<u>E</u>	<u>E</u>	=
c. Coagulation studies	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
d. Comprehensive blood bank or access to a community central blood bank	<u>E</u>	<u>E</u>	<u>E</u>	_
and adequate storage facilities		브	브	_
e. Blood gases and pH determinations	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
f. Microbiology	<u>E</u>	<u>E</u>	<u>E</u>	_
12. Acute Hemodialysis				
a. In-house	E	-	-	-
b. Transfer agreement	-	Ē	Ē	Ē
13. Burn Care—Organized		 ~	_=	_=
a. In-house or transfer agreement with burn center	Е	Е	Е	Е
	브	느느	브	<u> </u>
14. Acute Spinal Cord Management		-		
a. In-house or transfer agreement with regional acute spinal cord injury	E	<u>E</u>	<u>E</u>	<u>E</u>
<u>rehabilitation center</u>	_			

F.	Rehabilitation Services				
	1. Transfer agreement to an approved rehabilitation facility	E	<u>E</u>	<u>E</u>	E
	2. Physical therapy	<u>E</u>	E	E	-
	3. Occupational therapy	<u>E</u>	E	_	-
	4. Speech therapy	E	E	_	
	5. Social Services	E	E	Ē	_
G.	Performance Improvement		_	_	_
	Performance improvement programs	E	E	E	E
	2. Trauma Registry		_	_	
	a. In-house	E	<u>E</u>	<u>E</u>	<u>E</u>
	b. Participation in state, local, or regional registry	<u>E</u>	E	<u>E</u>	<u>E</u>
	3. Audit of all trauma deaths	<u>E</u>	E	<u>E</u>	<u>E</u>
	4. Morbidity and mortality review	E	<u>E</u>	E	E
	5. Trauma conference – multidisciplinary	E	<u>E</u>	<u>E</u>	<u> </u>
	6. Medical nursing audit	E	<u>E</u>	<u>E</u>	Ē
	7. Review of prehospital trauma care	E	<u>E</u>	<u>E</u>	
	8. Review of times and reasons for trauma-related bypass	E	<u>E</u>		_
	9. Review of times and reasons for transfer of injured patients	E	<u>E</u>	E	<u> </u>
	10. Performance improvement personnel dedicated to care of injured patients	E E	E	-	<u> </u>
Н.	Continuing Education/Outreach		=	_	_
	1. Outreach program ¹⁰	<u>E</u>	<u>=</u>	<u>=</u>	=
	2. Residency program ¹¹	<u>E</u>	=	_ _	_
	3. ATLS provide/participate	E E	<u>-</u>	_ _	=
	4. Programs provided by hospital for:	<u> </u>	_	_	_
	a. Staff/community physicians (CME)	<u>E</u>	<u>E</u>	E ¹²	=
	b. Nurses	<u>E</u>	<u>E</u>	<u>E</u>	
	c. Allied health personnel	E	<u>E</u>	<u>E</u>	_
	d. Prehospital personnel provision/participation	E E	E	E	
Ī.	Prevention-	<u> </u>		<u> </u>	_
	1. Prevention program ¹³	<u>E</u>		=	=
	Injury control studies	E	<u>E</u>		
	3. Collaboration with other institutions	E	<u>E</u>	<u>-</u>	=
	4. Monitor progress/effect of prevention programs	E	<u>E</u>	<u>-</u>	
-	5. Designated prevention coordinator – spokesperson for injury control	<u>E</u>	<u>E</u>	<u>-</u> -	=
	6. Outreach activities	E	<u>E</u>	<u>-</u>	=
	7. Information resources for public	E	<u>E</u>	<u>-</u>	
-	8. Collaboration with existing national, regional, and state programs	E	E	E	Ē
-	9. Coordination and/or participation in community prevention activities	E E	E	<u>E</u>	<u> </u>
J.	Research	<u> </u>	<u> </u>	<u> </u>	
<u> </u>	1. Research program ¹⁴	<u>E</u>	_	_	_
-	Trauma registry performance improvement activities	<u>E</u>	<u>E</u>	<u>E</u>	
	3. Identifiable Institutional Review Board process	<u>E</u>	<u> </u>	<u> </u>	
	Extramural education presentations	<u>E¹⁵</u>	-	-	
K.	Additional Requirements for Trauma Centers Represented as Caring for	<u>-</u>	=	=	=
17.	Pediatric Trauma Patients Pediatric Trauma Patients				
	Trauma surgeons credentialed for pediatric trauma care	<u>E</u>	<u>E</u>	_	_
	Pediatric emergency department area	<u>E</u>	<u>E</u>	-	-
	Pediatric resuscitation equipment in all patient care areas	<u>E</u>	<u>E</u>	-	-
	4. Microsampling	<u>E</u>	<u>E</u>	E	_
	5. Pediatric-specific performance improvement program	<u>E</u>	E	E	<u> </u>
	6. Pediatric intensive care unit	$\frac{\underline{E}}{E^{16}}$	$\frac{\underline{L}}{E^{\underline{17}}}$		<u> </u>
	6. I coloure intensive care unit	브	ᆫ브		

22

- Meets the following:
 - a. Has a letter written by the trauma director demonstrating that the health care institution's trauma program has a critical need for the physician because of the physician's individual experience or the limited physician resources available in the physician's specialty;
 - b. Has successfully completed an accredited residency training program in the physician's specialty, as certified by a letter from the director of the residency training program;
 - c. Has current ATLS certification as a provider or instructor, as established by documentation;
 - d. Has completed 48 hours of trauma CME within the past three years, as established by documentation;
 - e. Has attended at least 50% of the trauma quality assurance and educational meetings, as established by documentation:
 - f. Has been a member or attended local, regional, and national trauma organization meetings within the past three years, as established by documentation;
 - g. Has a list of patients treated over the past year with accompanying ISS and outcome for each;
 - h. Has a quality assurance assessment by the trauma director showing that the morbidity and mortality results for the physician's patients compare favorably with the morbidity and mortality results for comparable patients treated by other members of the trauma service; and
 - i. Has full and unrestricted privileges in the physician's specialty and in the department with which the physician is affiliated; or
- Meets the following: <u>2.</u>
 - a. Has provided exceptional care of trauma patients, as established by documentation such as a quality assurance assessment by the trauma director;
 - b. Has numerous publications, including publication of excellent research;
 - c. Has made numerous presentations; and
 - d. Has provided excellent teaching, as established by documentation.

- 1. 1200 trauma admissions per year,
- <u>2.</u> 240 admissions with ISS > 15 per year, or
- An average of 35 patients with ISS > 15 for the trauma panel surgeons per year.

Burn patients may be included in annual trauma admissions if the trauma service, not a separate burn service, is responsible for burn care in the trauma center.

⁶ 24-hour in-house availability of the attending surgeon is the most direct method to ensure compliance with this standard. A PGY 4 or 5 resident may begin resuscitation while awaiting the arrival of the attending surgeon, but cannot be considered a replacement for the attending surgeon in the emergency department. The attending surgeon is required to participate in major therapeutic decisions, be present in the emergency department for major resuscitations, and be present at all operative procedures.

A major resuscitation includes a patient:

- 1. If an adult, with a confirmed blood pressure < 90 at any time or, if a child, with confirmed age-specific hypotension;
- With respiratory compromise, respiratory obstruction, or intubation;
- <u>3.</u> Who is transferred from another hospital and is receiving blood to maintain vital signs;
- Who has a gunshot wound to the abdomen, neck, or chest;
- <u>4.</u> <u>5.</u> Who has a Glasgow Coma Scale score < 8 with a mechanism attributed to trauma; or
- Who is determined by an emergency physician to be a major resuscitation.

¹ When emergency medicine physicians do not participate in the care of a hospital's trauma patients, they are not required to be immediately available 24 hours per day.

² This requirement may be satisfied by a transfer agreement.

 $[\]frac{3}{2}$ A non-board-certified physician may be included in the trauma service if the physician either:

⁴ A physician who is board-certified in emergency medicine is not required to have current ATLS certification.

⁵ Except for Level I trauma centers that care only for children, each Level I trauma center shall satisfy one of the following volume performance standards:

⁷ A trauma center that does not admit pediatric patients shall be capable of resuscitating, stabilizing, and transporting

pediatric trauma patients.

- ⁸ A Level I trauma center shall have an adequately staffed operating room immediately available. This is met by having a complete operating room team in the hospital at all times, so that an injured patient who requires operative care can receive it in the most expeditious manner. The members of the operating room team shall be assigned to the operating room as their primary function; they cannot also be dedicated to other functions within the institution.
- ⁹ This requirement may be satisfied by a physician authorized by the hospital to admit patients into the intensive care unit as the attending physician or to perform critical care procedures.
- $\frac{10}{2}$ This requirement may be met by participating in a collaborative outreach program that includes multiple hospitals.
- 11 A Level I trauma center shall have a functional and documented teaching commitment. This requirement may be met through:
- 1. A trauma fellowship program; or
- 2. Active participation with one of the following types of residency programs in emergency medicine, general surgery, orthopaedic surgery, or neurosurgery:
 - a. A regional residency rotation program; or
 - <u>b.</u> A collaborative residency program that includes multiple hospitals, with each non-sponsor participating hospital hosting at least one rotation.
- ¹²When a Level III trauma center is in an area that contains a Level I or Level II trauma center, this is not required.
- 13 This requirement may be met by participating in a collaborative prevention program that includes multiple hospitals or in a program sponsored or coordinated by the Regional Trauma Councils.
- 14 This requirement may be met by participating in a regional research program or a collaborative research program that includes multiple hospitals.
- 15 The trauma program shall provide 12 educational presentations every three years outside the academically affiliated institutions of the trauma center.
- 16 The trauma center shall have a PICU available on-site.
- 17 This requirement may be satisfied by a transfer agreement.